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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/656,540

09/05/2003

Steve Koh

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PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER

FLORY, CHRISTOPHER A

ART UNIT

PAPER NUMBER

3762

MAIL DATE

DELIVERY MODE

04/09/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/656,540

Applicant(s)

KOH ET AL.

Examiner

CHRISTOPHER A. FLORY

Art Unit

3762

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 March 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 3-5, 7, 8 and 25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 3-5, 7, 8 and 25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Response to Amendment

1. The finality of the rejection of the last Office action is withdrawn based on the amendments presented by Applicant as well as newly discovered prior art references.

Response to Arguments

2. Applicant's arguments with respect to claims 3-5, 7, 8 and 25 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 4, 5, 7, 8 and 25 are rejected under 35 U.S.C. 102(e) as being anticipated by King et al. (US 7,155,278, hereinafter King'278).

Regarding claims 7 and 25, King'278 teaches a method and implantable device for cardiac stimulation (Figs. 1, 5-7) comprising delivering one or more pacing pulses to an atrium (column 2, lines 62-64; column 3, lines 47-67); determining one or more atrioventricular conduction interval times based on the pacing pulses (column 6, lines 7-

Art Unit: 3762

31); determining a respiratory characteristic based at least in part on the AVI times (claim 10); and discriminating between obstructive apnea and central apnea (column 1, lines 10-30; column 2, lines 5-26; column 6, lines 7-31).

Regarding claim 8, King'278 discloses discriminating apnea based in part on a measurement related to chest movement (column 5, lines 43-65).

Regarding claims 4 and 5, King'278 discloses a pacing rate that is varied with respect to a time-based intrinsic rate (column 2, lines 47-67; column 6, lines 17-31; column 7, lines 15-31).

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 4, 5, 7, 8 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. in view of Warner et al., "Beat-by-Beat Modulation..." (hereinafter referred to as Warner and Loeb; for full citation, see page 2 of the IDS submitted by Applicant on 5 September 2003) and further in view of King'278.

Regarding claims 7 and 25, Thornander et al. discloses a method comprising delivering one or more pacing pulses to an atrium (ABSTRACT; column 2, line 67 through column 3, line 7); determining one or more atrioventricular conduction interval times based on the pacing pulses (ABSTRACT; column 3, lines 37-45); and determining

Art Unit: 3762

a respiratory characteristic based at least in part on the AV conduction interval times (column 21, line 65 through column 22, line 10; column 23, lines 7-8; column 2, lines 47-51; column 3, lines 20-30; column 3, lines 65-68).

It is noted that increased workload and changes in heart rate as disclosed in Thornander et al. are being understood as respiratory characteristics, because increased workload (i.e. exercise) produces an increased respiratory frequency, while it is known that heart rate is an indicator of respiratory state, since inhalation raises the instantaneous heart rate slightly, while exhalation decreases instantaneous heart rate.

Further regarding claims 7 and 25, Thornander et al. discloses the instant invention substantially as claimed except that the respiratory cycle length is determined based on the atrioventricular conduction interval times. In the same field of endeavor, Warner and Loeb teaches that AV interval shows a 1-to-1 correlation to the respiratory cycle length both with and without pacing (page 1127, col.2, paragraph 4 through page 1128, end of column 2; p. 1131, col. 2, paragraph 1; Fig. 1). It follows that a change or trend in AV conduction interval times would be sufficient to determine a relative respiratory cycle length. Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Thornander et al. to determine respiratory cycle length based on a comparison of AVIs as disclosed in Warner and Loeb since it has been shown in Warner and Loeb that a change in respiratory cycle length correlate in a 1-to-1 manner to a specific change in AV conduction interval times and vice versa.

Further regarding claims 7 and 25, Thornander et al. discloses the invention substantially as claimed, but does not expressly disclose that the respiratory characteristic based on atrioventricular conduction interval times is used to discriminate between obstructive apnea and central apnea. In the same field of endeavor, King'278 teaches distinguishing between central and obstructive apneas, as well as monitoring atrioventricular conduction times to detect the occurrence of apneas (column 1, lines 10-30; column 2, lines 5-26; column 6, lines 7-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Thornander et al. to include detection of central and obstructive apneas based on atrioventricular conduction times as taught by King'278 to provide Thornander et al. with the same advantages of identifying apnea occurrences.

Regarding claim 4, Thornander et al. discloses that the atrial pacing occurs at a rate that varies with respect to an intrinsic rate (ABSTRACT; column 2, line 47 through column 3, line 6).

Regarding claim 5, the pacemaker of Thornander et al. varies the atrial pacing rate in response to intrinsic rates that change over a given time period based on increased or decreased physiologic demands. Because the rates on which the pacing is based vary with respect to time, the atrial pacing rate can also be said to vary with respect to time. Therefore, the claim limitation of the instant claim does not distinguish over the prior art.

Regarding claim 8, King'278 teaches discriminating apnea based in part on a measurement related to chest movement (column 5, lines 43-65).

Art Unit: 3762

Further regarding claim 25, Thornander et al. shows an implantable cardiac stimulation system (Fig. 10, pacemaker 16) comprising sensing circuitry operative to sense atrial and ventricular events (P-wave sense/pace amp 48, R-wave sense/pace amp 56); a processor connected to the sensing circuitry (Fig. A-1, microprocessor 408) operative to determine one or more A-V conduction interval times based on the delivered stimulation pulses (ABSTRACT; column 3, lines 37-45) and further operative to determine a respiratory characteristic based at least in part on the A-V interval times (column 21, line 65 through column 22, line 10; column 23, lines 7-8; column 2, lines 47-51; column 3, lines 20-30; column 3, lines 65-68); and further comprising a pulse generator operative to generate stimulation pulses for delivery to a patient's heart (Fig 10, pulse generator logic 42 and pulse output driver circuits 44 connected to heart 18), and at least one electrode (atrial lead 22 with tip electrode 24; ventricle lead 30 with electrode 46).

7. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Thornander et al. in view of Warner and Loeb, f.i.v. King'278, and further in view of Applicant's own admitted prior art (Admission).

Thornander et al. discloses the instant invention substantially as claimed but does not expressly state that atrial pacing occurs at a frequency that is at least double the respiratory frequency. Admission teaches that according to signal sampling theory, the sampling frequency must be greater than twice the maximum frequency of the sampled behavior in order to sufficiently avoid frequency aliasing (paragraph [68]). In this case, this theory applies in that the AV Interval, which represents the sample of the

Art Unit: 3762

respiratory characteristic, must be calculated at greater than double the frequency of the respiratory cycle, which inherently means that atrial pacing must occur at double the respiratory frequency (because one AV Interval is sampled for each atrial pacing pulse delivered). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system disclosed in Thornander et al., with the pacing frequency of at least double the respiratory frequency in Admission, for the advantage of avoiding frequency aliasing and the resultant of improper determination of the respiratory characteristic (motivation to combine provided by Admission, paragraph [68]).

8. Claims 7, 8 and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al. in view of Warner and Loeb, and further in view of King'278.

Regarding claims 7 and 25, Lurie et al discloses a method comprising delivering one or more pacing pulses to an atrium (column 3, lines 42-53); determining one or more A-V conduction interval times and determining a respiratory characteristic based at least in part on the one or more conduction interval times (ABSTRACT; column 2, lines 24-38; Figures 3-6); wherein the respiratory characteristic comprises a respiratory cycle length (column 2, line 31—respiration rate is being taken by definition to be a well-known mathematical equivalent to respiratory cycle length, because a patient with a respiration rate of 10 breaths per minute has with mathematical certainty a respiratory cycle length of 6 seconds). Lurie et al. discloses the instant invention substantially as claimed except for determining whether the respiratory characteristic (respiratory cycle length) indicates apnea. In the same field of endeavor, Warner and Loeb teaches that

Art Unit: 3762

AV interval shows a 1-to-1 correlation to the respiratory cycle length both with and without pacing (page 1127, col.2, paragraph 4 through page 1128, end of column 2; p. 1131, col. 2, paragraph 1; Fig. 1). It follows that a change or trend in AV conduction interval times would be sufficient to determine a relative respiratory cycle length.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Lurie et al to determine respiratory cycle length based on a comparison of AVIs as disclosed in Warner and Loeb since it has been shown in Warner and Loeb that a change in respiratory cycle length correlate in a 1-to-1 manner to a specific change in AV conduction interval times and vice versa.

Further regarding claims 7 and 25, Lurie et al discloses the invention substantially as claimed, but does not expressly disclose that the respiratory characteristic based on atrioventricular conduction interval times is used to discriminate between obstructive apnea and central apnea. In the same field of endeavor, King'278 teaches distinguishing between central and obstructive apneas, as well as monitoring atrioventricular conduction times to detect the occurrence of apneas (column 1, lines 10-30; column 2, lines 5-26; column 6, lines 7-31). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system as taught by Lurie et al. to include detection of central and obstructive apneas based on atrioventricular conduction times as taught by King'278 to provide Lurie et al. with the same advantages of identifying apnea occurrences.

Regarding claim 8, Lurie et al. discloses measurements related to chest movement (column 2, lines 22-23).

Art Unit: 3762

9. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lurie et al. in view of Warner and Loeb, f.i.v. King'278, and further in view of Applicant's own admitted prior art (Admission).

Lurie et al. discloses the instant invention substantially as claimed but does not expressly state that atrial pacing occurs at a frequency that is at least double the respiratory frequency. Admission teaches that according to signal sampling theory, the sampling frequency must be greater than twice the maximum frequency of the sampled behavior in order to sufficiently avoid frequency aliasing (paragraph [68]). In this case, this theory applies in that the AV Interval, which represents the sample of the respiratory characteristic, must be calculated at greater than double the frequency of the respiratory cycle, which inherently means that atrial pacing must occur at double the respiratory frequency (because one AV Interval is sampled for each atrial pacing pulse delivered). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system disclosed in Lurie et al., with the pacing frequency of at least double the respiratory frequency in Admission, for the advantage of avoiding frequency aliasing and the resultant of improper determination of the respiratory characteristic (motivation to combine provided by Admission, paragraph [68]).

10. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over King'278 in view of Applicant's own admitted prior art (Admission).

King'278 discloses the instant invention substantially as claimed but does not expressly state that atrial pacing occurs at a frequency that is at least double the respiratory frequency. Admission teaches that according to signal sampling theory, the

Art Unit: 3762

sampling frequency must be greater than twice the maximum frequency of the sampled behavior in order to sufficiently avoid frequency aliasing (paragraph [68]). In this case, this theory applies in that the AV Interval, which represents the sample of the respiratory characteristic, must be calculated at greater than double the frequency of the respiratory cycle, which inherently means that atrial pacing must occur at double the respiratory frequency (because one AV Interval is sampled for each atrial pacing pulse delivered). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the system disclosed in King'278, with the pacing frequency of at least double the respiratory frequency in Admission, for the advantage of avoiding frequency aliasing and the resultant of improper determination of the respiratory characteristic (motivation to combine provided by Admission, paragraph [68]).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3762

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

9 April 2008

/George Manuel/
Primary Examiner